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| 09/941,626 | 08/30/2001 | Norman G. Anderson | 42159 | 6779 |

7590 05/04/2004
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EXAMINER

MARSCHER, ARDIN H

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1631

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

MS

Office Action Summary

Application No.

09/941,626

Applicant(s)

ANDERSON ET AL.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 16, 59 and 63-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 16, 59 and 63-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed 2/6/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

NEW MATTER

Claims 63 and 65-68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

NEW MATTER has been amended into the claims via newly added claim 63. Claim 63 indicates that the individuals are humans and depends from claim 2. Consideration of claim 2 reveals that a sample being analyzed is a mixture of biological samples from plural individuals. Consideration of the entirety of the instant disclosure as filed has failed to reveal a mixture of such samples from plurals humans as now required in the newly added claim 63. Thus, claim 63 contains NEW MATTER. This rejection is necessitated by amendment.

Claim 65 newly adds the limitation that the database contains "different unrelated known infectious particles". Within this phrase the limitation "unrelated" has not been found as filed regarding such database contents. Thus, this phrase contains NEW

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MATTER as there is no written basis as filed for "unrelated" different known infectious particles in a database. This rejection is necessitated by amendment.

In claim 66 the citation of samples which are "not suspected of containing a specific infectious particle" is present as a newly added limitation. Consideration of the entirety of the instant disclosure as filed has failed to reveal such "not suspected...specific infectious particle" limitation. Thus, this phrase contains NEW MATTER as there is no written basis as filed for said phrase. This rejection is necessitated by amendment.

In newly added claim 67 the limitation "at least part of a non-coding sequence of the infectious particle" has been set forth. Consideration of the entirety of the instant disclosure as filed has failed to reveal such "at least part of a non-coding sequence...particle" limitation. Thus, this phrase contains NEW MATTER as there is no written basis as filed for said phrase. This rejection is necessitated by amendment.

In newly added claim 68 the limitation "immobilized oligonucleotide microarray" is set forth. Consideration of the entirety of the instant disclosure as filed has failed to reveal such an "immobilized oligonucleotide microarray" limitation. A more limited microarray disclosure has been found in the specification on page 24, line 15, therein set forth as "immobilized DNA microarrays". Thus, this phrase contains NEW MATTER as there is no written basis as filed for said broadened limitation compared to what has been filed. This rejection is necessitated by amendment.

VAGUENESS AND INDEFINITENESS

Claims 1-14, 16, 59, and 63-68 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is necessitated by the amendment of claim 1, last line, to cite "plural sequenced nucleic acids". This amendment may be interpreted as being set forth to clarify the antecedent basis as to what is meant by plural nucleic acids, as also argued by applicants. Said amendment, however, is confusing because in lines 5-6 of claim 1 sequencing is practiced only for "at least a portion of the at least two nucleic acids...thereof". Thus, there is no "sequenced" nucleic acids per se to supply clear antecedent basis for said phrase in the last line of claim 1. Partially sequenced, possible fully sequenced, nucleic acids are cited in said lines 5-6 of claim 1. One customary and reasonable interpretation of "sequenced nucleic acids" is fully sequenced nucleic acids. Therefore, do the last two lines of claim 1 refer only to those fully sequenced nucleic acids from lines 5-6 of claim 1 and not the others which are partially sequenced? Clarification via clearer claim wording is requested. Claims dependent directly or indirectly from claim 1 are also rejected herein under due to their dependence.

The rejection based on unclarity regarding "complementary" is maintained and reiterated from the previous office action, mailed 11/5/03. Applicants have explained what is desired for the practice of "complementary" but have not amended the claim as such thus leaving the claim unclear on this issue. Additionally, the clarifying argument that applicants do not intend a definition that renders the claimed method inoperable

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has not been found as filed and thus cannot be properly added as a limitation at this time which is well after the date of filing of the instant application. Clarification via clearer claim wording is requested. Claims dependent directly or indirectly from claim 1 are also rejected herein under due to their dependence.

PRIOR ART

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 4, 6, 7, 9, 10, 12, 13, 59, 63, and 64 are rejected under 35 U.S.C. 102(b) and (e)(2) as being clearly anticipated by Reyes et al. (P/N 5,218,099).

This rejection is reiterated and maintained from the previous office action, mailed 11/5/03, and as necessitated by amendment regarding newly added claims. Applicants argue firstly that the instantly claimed method is directed to identifying a plurality of infectious particles contrary to Reyes et al. In order to understand this argument, the intended meaning of plurality as argued by applicants must be interpreted. Apparently, applicants may intend that the "plurality" limitation is directed to a plurality of infectious particles which differ in some characteristic or which are "different types" of such particles. In response instant claim 1 does not contain any such different type

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limitation(s) nor differing limitation directed to particle characteristics. This argument therefore is directed to limitations which are not in the claims and therefore non-persuasive. Another interpretation of a plurality of infectious particles is reasonably derived from the well known sample contents of infectious particles wherein a sample contains a multitude of such particles, maybe different, and maybe of the same type. Additionally in response it is understood to be a rare sample that contains only a single infectious particle of any type therein, or, even of each type in a mixed sample of infectious particles. The methodology of Reyes et al. purifies a multitude of infectious particles via bulk methods such as centrifugation and thus anticipates the instant claim limitations wherein a plurality of infectious particles are purified etc. as pointed out in said previous office action. Thus, in summary, the above arguments are non-persuasive to distinguish the instant claims over Reyes et al. Even if applicants added limitations directed to said plurality comprising infectious particles which differ in type or characteristics, the Reyes et al. disclosure is not limited to one infectious particle type because Figures 1-5 as previous cited in the bridging sentence between columns 2 and 3 disclose sequences from different sequence containing viruses specimens, albeit all apparently being of the PT-NANB species. These five different sequences as previously set forth also continue to document anticipation of the "at least two nucleic acids" limitation of the instant claims. Applicants argue that the identity of the virus particles are not determined by sequencing. In response as noted in the previous office action as well as further explained above five different viruses were identified in Figures 1-5 via their differing sequences contrary to applicants' allegation. Differing sequence

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viruses, even within a single PT NANB specie of virus, are reasonably interpreted as differing infectious particles.

Applicants then argue that the comparison between few samples and another publication is not comparison to a database as known by most people. No such limitation as to the lower size of a database has been instantly set forth nor that a database must be of the type known by most people. Thus, this argument is directed to limitations not disclosed as filed nor set forth in the instant claims, and therefore is non-persuasive. Applicants further argue that said database comparison is not a comparison to "known infectious particles". In response this argument conflicts with applicants own previous argument that Reyes et al. performs a comparison to a few samples described in the disclosure of Reyes et al. which supports the interpretation that these are known infectious particles as being sequenced already and identified via said sequencing as well as by antibody as also argued by applicants. Therefore this argument is non-persuasive regarding distinguishing this limitation over Reyes et al. Applicants go on to argue that there is no "simultaneously" detection practice in the reference. In response Reyes et al. performs bulk isolation and detection of viruses from samples and thus simultaneously detects a multitude of infectious particles in such a method. It is again noted from above that even if a particular sample only results in one sequence of virus of each type that such a sequencing identification serves to identify all of the same virus, a plurality of them, in such a sample.

Applicants lastly argue that no special containment system is utilized in Reyes et al. This argument is apparently directed to instant claim 59. Consideration of claim 59

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reveals that it lacks any "special" limitation regarding its recited containment system.

Thus, the argument regarding "special" containment system in claim 59 lacks correspondence to the actual claim wording and thus non-persuasive. Regarding the generic "containment system" limitation in claim 59, it was set forth in the previous office action, mailed 11/5/03, that centrifugation is well known to be performed in a containment system. No argument to this basis for rejection has been set forth by applicants. Therefore, applicants' argument regarding this issue is non-persuasive.

Claim 63 is added as rejected hereinunder as necessitated by amendment in that in column 2, lines 41-46, serum (singular) from infected humans is utilized for obtaining virus particles as also required in such a sample which inherently must be a mixture if a singular serum sample is utilized for virus particle obtaining practice.

Claim 64 is added as rejected hereinunder as necessitated by amendment because density gradient centrifugation is practiced as disclosed by Reyes et al. in column 2, lines 58-66.

INFORMALITIES

The disclosure is objected to because of the following informalities:

In the specification on page 17, line 4, the abbreviation "PCT" appears misspelled in context.

In claim 59, line 1, the phrase "claims 1" contains the conflict of the word "claims" being plural in form vs. only one claim, that is, claim 1, being cited thereafter.

Appropriate correction is required.

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Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

April 30, 2004

Ardin H. Marschel
ARDIN H. MARSCHEL
4/30/04